## REMARKS/ARGUMENTS

Reconsideration of this application is requested. Claims 38-81 are in the case.

## I. THE ANTICIPATION REJECTION

Claims 38-76 stand rejected under 35 U.S.C. §102(e) as allegedly anticipated by U.S. Patent 6,106,466 to Sheehan et al. That rejection is respectfully traversed.

The method of the invention is directed to assessing one or more characteristics of an organ or part thereof from multiple images of the organ or part thereof. The method comprises the steps of defining the spatial position of at least two of the images, forming an initial fit between a reference model of the geometric shape of the organ or part thereof and the images according to reference markers on the images, manually user-defining one or more reference guide points associated with one or more images displayed to a user, for which the spatial positions have been defined, converting the guide points to three-dimensional coordinates, improving the fit of the model by fitting the model to the guide points to form an estimate model for the organ or part; and assessing the one or more characteristic from the estimate model.

Sheehan does not anticipate the methodology as claimed. Sheehan describes a method for defining a 3-dimensional surface of a patient heart. An ultrasound machine in combination with an ultrasound transducer produces ultrasound waves that are converted into a corresponding signal by the ultrasound transducer. Images of the patient heart are obtained from this signal (column 8, lines 19 to 32). The spatial position of each image is stored in non-volatile memory to enable a CPU to compute the

3-dimensional coordinates of every pixel comprising each image frame (column 9, lines 3 to 9).

Sheehan attempts to automatically detect the borders of the left ventricle of the heart within the images and attempts to produce a 3-dimensional shape contour of that organ based upon the ultrasound scan of the heart of the patient (column 11, lines 29 to 35). Three points representing specific anatomic landmark structures are manually traced by the user in these images, producing a set of three x y coordinates. The specific anatomical landmarks in the left ventricle are the center of the aortic valve, center of the mitral valve and the ventricular apex (column 11, lines 38 to 44).

Sheehan describes the use of a knowledge base created by manually tracing multiple ultrasound images of subject hearts. The Sheehan et al model is a mesh model derived from a plurality of traced population hearts (column 12).

The mesh is aligned to each of the obtained images using the three traced points or anatomical landmarks in each image (column 14, lines 53 to 56). The model is used to estimate an ideal gray scale appearance and expected deviation from a stereotypical patient heart. The generated image model is rotated, translated and scaled as necessary to attempt to align the anatomical landmarks in the predicted images derived from the mesh model with the corresponding anatomical landmarks in the corresponding images of the patient heart (column 15, lines 2 to 10).

Without further input from the operator, the system described in Sheehan et al performs automatic border detection in an attempt to further refine the match between the mesh model and the image data for the patient. Feature extraction to locate edge boundaries is performed using an edge operator (column 15, lines 25 to 28).

Comparison between the predicted patient image and the actual patient image is performed automatically using feature extraction.

The mesh model is then manipulated in an attempt to achieve a match between the predicted image created from the mesh model and the corresponding images of the patient heart. This manipulation involves adjusting the control vertices of the mesh model (column 15, lines 65 to column 16, line 4). The predicted model is continually adjusted until the mesh model produces predicted images that match the images of the patient heart with an error within a predefined threshold (column 16, lines 50 to 53). The mesh model is continually adjusted until the model produces a 3-dimensional surface that best represents the shape of the patient heart, defined by minimising error (column 17, lines 14 to 17).

As a final test, the user is able to determine if the results are acceptable by reviewing the intersection of the 3-dimensional surface of the adjusted mesh model with the desired plane of the image. If the border is not acceptable, the operator is provided with the option to manually edit the abstract mesh of the mesh model to achieve a still closer match between resulting predicted images and the observed images of the patient heart (column 17, lines 20 to 32). There is no description in Sheehan et al as to the nature of this manual editing performed by a user. The manual editing is presumably a manual tracing of the generated image or images.

Sheehan et al performs adjustment of the predicted images automatically in an attempt to develop a reliable predicted model of the image heart. The user is only able to provide input into the model adjustment at the end of the process. Sheehan et al suggests that little or no user intervention will be required. Applicants believe that, in

practice, the Sheehan model would not generate a predicted model that is sufficiently close to a patient heart and that significant user input will be required to increase the match. If significant user input is required, then the utility of the Sheehan et al model is significantly reduced.

The present invention as claimed in claim 38 is directed to a method of assessing one or more characteristics of an organ or part thereof from multiple images of the organ or part thereof. Claim 50 is directed to a related system for assessing one or more characteristics of an organ or part thereof and claim 62 is directed to a related computer program for assessing one or more characteristics of an organ or part thereof.

The respective spatial positions of the images are first determined and then an initial fit is formed between a reference model of the geometric shape of the organ or part thereof and the subject images. The user defines reference marks on the images, for example a point representing the base in the model's cardiac coordinate system, and a point representing the apex in the same system. The method could include the step of calculating a landmark such as the long axis defined by a line in 3-dimensional space between the two points selected by the user. The reference model is fitted to the images, for example by scaling the model according to the length of the long axis defined between the two user selected points. The model is aligned with the patient images, for example by positioning the model along the central axis defined by the user.

The model defined by the system is a model generated interactively and quickly from two or more user defined points in actual images. The model does not depend to a great extent on edge detection in the images. Applicant submits that edge detection is often unreliable in cases where the images are not clear or are blurred.

The intersection between the scanned images and the model surfaces are presented to a user. The user defines one or more reference guide points associated with the images for which spatial positions have been defined. These guide points could include, for example, boundary guide points that define the endocardial or epicardial boundaries of the heart. The user is able to view the endocardial and epicardial boundaries of the heart and to quickly define boundary guide points associated with these images. Manual tracing of the boundaries is not required.

The present invention as claimed in new claim 77 is also directed to a method of assessing one or more characteristics of an organ or part thereof for multiple images of the organ or part thereof. Claim 77 includes the feature of displaying one or more images to a user and superimposing on the image a representation of the intersection of the reference model with the image.

Sheehan describes producing predicted images from a mesh model. The mesh model produces a gray scale image that predicts the appearance of the scan ultrasound image (column 14, lines 64 to 66). In this way, the mesh model is used to produce predicted images corresponding to the images of the patient's heart made in specific imaging planes. The predicted and observed images are then compared (column 15, lines 23 and 24).

By contrast, the present invention as defined in new claim 77 does not generate a predicted image from the mesh model. Rather, the present invention calculates a reference model and superimposes on an actual obtained image a representation of the intersection of the surfaces of the reference model with the image plane of that image.

This image with the representation of the intersection superimposed on the image is then presented to a user.

The present invention involves an interactive process. As the user defines these boundary guide points, the guide points are converted to 3-dimensional coordinates. The user-defined boundary points are compared with those predicted by the model. The present invention does not rely on image processing to identify the predicted and actual surfaces of the organ. The present invention instead compares the user-defined points on the surface that are generally more accurate than those extracted automatically from a subject image.

The fit of the predicted model is then improved by fitting the model to the user-defined boundary guide points to form an estimate model for the organ.

The estimate model can then be used to assess one or more characteristics, for example volume, wall thickness and/or mass of the organ or part thereof.

The present invention does not use an estimate model derived from an extension knowledge base created by manually tracing multiple ultrasound images of subject hearts. The present applicants have developed a geometric shape that accurately represents the subject organ or part thereof.

Sheehan leads away from use of a geometric shape as a reference model. Specifically, Sheehan describes that one prior art system cannot capture the complex anatomic shape of the ventricle (column 4, lines 34 and 35). Sheehan also describes that other models have been developed that are based on parametric functions, superquadratics or finite element models but that these models require many terms to accurately represent complexities in ventricular shape (column 4, lines 36 to 39).

Sheehan further discloses that a further prior art model, the active shape model, can only be deformed in ways that are consistent with the statistical model derived from training data (column 5, lines 15 to 18).

The applicants have developed a computationally cost-effective geographic model as an initial reference model for the organ or part thereof. Applicants submit that the Sheehan model would not be fast enough to satisfy the requirements of a user. Applicant has developed a geometric shape that works well in practice, in spite of Sheehan teaching away from such practice.

The present invention provides a computationally cost-effective method of measuring characteristics of an organ by first generating an optimised model of that organ. The user is involved in an interactive process in developing the model so that the input of the user is obtained in real time and at an early stage in development of the model. Prior art techniques such as that described in Sheehan et al are not effective if the images are not clear, as Sheehan et al relies on image processing and other automatic analysis of the images. The Sheehan et al model requires editing following automated model generation. This editing is often time-consuming and is often longer in duration than creating a model entirely manually.

In light of the above, it is clear that the invention as claimed is not anticipated (or rendered obvious by) Sheehan. Withdrawal of the outstanding anticipation rejection is accordingly respectfully requested.

## II. REQUEST FOR INTERVIEW

In order to expedite prosecution of the present application to a favorable conclusion, it is requested that an interview be granted in this case when the Examiner has reviewed the present response and prior to taking any further action in the application (unless the Examiner deems the application to be in condition for allowance). It is requested that the undersigned be telephoned at the number given below (703-816-4005) to arrange such interview.

Favorable action on this application is awaited.

Respectfully submitted,

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